



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration  
300 Pearl Street, Suite 100  
Buffalo, NY 14202

August 14, 2000

**WARNING LETTER NYK 2000-90**

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

John Tsujimoto, Vice President  
Oriental Wholesale Foods, Inc.  
6530 Seneca Street  
Elma, New York 14059

Dear Mr. Tsujimoto:

A U.S. Food and Drug Administration investigator conducted an inspection of your bean sprout production facility located at 6560 Seneca Street, Elma, New York on June 14 and 19, 2000. This inspection disclosed practices at your facility that cause your alfalfa and mung bean sprouts to be in violation Federal Food, Drug, and Cosmetic Act (the Act).

Specifically, our inspection revealed your sprouts are adulterated within the meaning of Section 402(a)(4) of the Act because they are being produced under insanitary conditions that may render the sprouts injurious to health. The conditions under which the sprouts are being produced are considered insanitary because effective preventive controls, particularly microbial testing of spent irrigation water have not been adopted and implemented at your facility. For example, you do not test spent irrigation water from alfalfa and mung bean sprout production for *Salmonella* and you do not test spent irrigation water from mung bean sprouts for *Escherichia coli* 0157:H7 (hereafter, *E. coli*).

We acknowledge your testing of spent irrigation water from the manufacture of alfalfa bean sprouts for *E. coli* using the [REDACTED]. However, we do not consider the test that you are using to be an effective equivalent to the test methods listed in the industry guidance document "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production." The testing procedures described in the guidance are screening tests. They were chosen to give results as quickly and as simply as possible on the presence or absence of *Salmonella* and *E. coli* 0157:H7. Sprouts and their irrigation water have a high level of natural microflora. The testing procedures described in the guidance involve an enrichment step to encourage the selective growth of pathogens, if they are present, to make their detection possible. FDA is not aware of any test kits

that will detect pathogens in spent irrigation water when an enrichment step is not performed. The [REDACTED] that you are using does not contain an enrichment step. In addition, you did not provide the investigator with data demonstrating the [REDACTED] equivalency to standard FDA Bacteriological Analytical Manual (BAM) methods for detecting *E. coli* 0157:H7 in spent irrigation water. If alternative kits are used, they should first be validated either by formal collaborative studies or by comparative studies with standard methods described in the BAM using the spent irrigation water or sprouts.

This violation may not be the only violation at your facility. It is your responsibility to ensure compliance with all applicable laws and regulations governing your products.

You should take prompt action to correct this violation. Failure to promptly correct this violation may result in FDA's taking regulatory action without further notice to you. This regulatory action may include seizure and/or injunction. I have enclosed copies of the guidance documents "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production" and "Reducing Microbial Food Safety Hazards for Sprouted Seeds" for your information and reference.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter of the steps you have taken to correct the noted violation, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the correction will be completed.

Your response should be directed to Lisa M. Utz, Compliance Officer, U.S. Food and Drug Administration, 300 Pearl Street, Suite 100, Buffalo, New York, 14202. If you have any questions regarding any issue in this letter, please contact Ms. Utz at (716) 551-4461 ext. 3165.

Sincerely,



Brenda J. Holman  
District Director

Enclosures